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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,318	11/07/2001	Erik Leonard Hoffman	05032-00011	4521

7590 11/15/2005

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EXAMINER

COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No.	Applicant(s)	
	10/037,318	HOFFMAN, ERIK LEONARD	
	Examiner	Art Unit	
	David Comstock	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,25-35,37-51 and 53-72 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,25-33,37,45-50,55 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 34,35,38-44,51,53,54 and 57-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34, 35, 38-44 and 58-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yapp (0 099 167; cited by Applicant).

Yapp discloses a fastening element 12 comprising a supporting element 24, a hollow pin 13, and fixing means 28. (See Figs. 1-7.) The supporting element has a bottom surface 22 that abuts sawn-off bone 42 and a top surface 26 that is flat and parallel to the bottom surface. The supporting element is thus plate shaped and also extends on at least two sides beyond an outer longitudinal edge of the pin (see Figs. 3 and 4). The angle between the longitudinal axis of the pin and the bottom surface of the plate is at approximately a 90 degree angle. The supporting element further comprises a coupling element 32 on a side remote from the pin. The pin extends from the supporting element into bone 42. The pin is at an angle with respect to a main surface of the supporting element (see Fig. 4). The pin is not symmetrical with respect to the longitudinal axis but rather is rectangular in cross section (see Figs. 3 and 4 and page 5, lines 2-5). The pin has a finish, i.e. porous bone contact surfaces 20, 22, to promote bone ingrowth into the hollow pin (see Figs. 1, 4, and 7 and page 3, lines 23-26). After

Art Unit: 3733

the bone ingrowth has occurred, both the outside and inside surfaces of the pin are in contact with bone tissue. The fixing means fixes the fastening element in position wherein the pin extends into bone. The fixing means comprises a screw 28 that screws into the pin from the side remote from the supporting element. The screw adjusts the tension of the fixing means. Yapp does not disclose the angle between the longitudinal axis of the pin and the bottom surface of the plate between about 125 and 145 degrees or the angular offset of the coupling element with respect to the longitudinal axis of the pin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an angle between the longitudinal axis of the pin and the bottom surface of the plate between about 125 and 145 degrees and to provide an angular offset, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It is noted that Applicant has not defined "largely" with sufficient specificity to preclude an interpretation of the pin of Yapp being "largely" hollow, since Yapp shows a pin with a hollow portion and the degree or ratio of hollow space has not been defined. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01.

Claims 51, 53, 54, 57 and 67-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masini (5,571,203)

Masini discloses a method of sawing a femur on a cut line 230 to create an abutment surface that extends at right angles to a load axis of a joint (see Figs. 2-4 and 6 and col. 6, lines 35-65). The hollow pin 312 of a fastening element 442 is driven into a hole formed in the bone such that a supporting element 226, to which the pin is attached, abuts the abutment surface. The supporting element has a bottom surface 228 and a top surface that is flat at least at its periphery and parallel to the bottom surface. The pin is driven in at a 90 degree angle with respect to the surface. The device is fixed from a remote side through cortical bone by a pin 250 introduced through cortical bone 214 and fixed to the device at a connection 234. Masini does not disclose the angle between the longitudinal axis of the pin and the bottom surface of the plate between about 125 and 145 degrees or the angular offset of the coupling element with respect to the longitudinal axis of the pin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an angle between the longitudinal axis of the pin and the bottom surface of the plate between about 125 and 145 degrees and to provide an angular offset, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 24 August 2005 have been considered but are not persuasive.

In response to Applicant's argument that neither Yapp nor Masini render obvious the claimed invention, it is noted that the test for obviousness is not whether the noted features may be bodily incorporated into the prior art device to arrive at the claimed subject matter, but simply what the references as a whole make obvious to one of ordinary skill in the pertinent art. Both Yapp and Masini disclose the general conditions or elements of the claimed invention, as set forth in the rejection. Where these references are lacking--for example, the angle of the pin with respect to the plate and the coupling element offset with respect to the pin--such parameters would merely involve routine skill in the art to determine, as already set forth in the rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3733

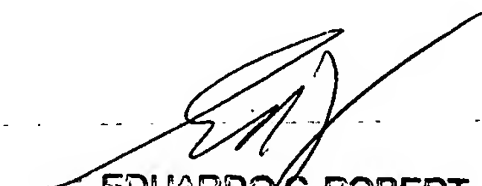
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock
12 November 2005



EDUARDO C. ROBERT
PRIMARY EXAMINER